EXHIBIT A

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HBorochoff v. GlaxoSmithKline PLC
S.D.N.Y.,2008.
Only the Westlaw citation is currently available.
United States District Court,S.D. New York.
Leon D. **BOROCHOFF**, Individually and On Behalf of All Others Similarly Situated, Plaintiff,
v.
GLAXOSMITHKLINE PLC, Dr. Jean-Pierre Garnier, David Stout, Simon Bicknell, and Julian Heslop, Defendants.
No. 07 Civ. 5574(LLS).

May 9, 2008.

OPINION and ORDER

LOUIS L. STANTON, District Judge.
***1** In this putative class action alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5, defendants move to dismiss the Amended Complaint pursuant to Fed.R.Civ.P. 12(b)(6) for failure to state a claim upon which relief can be granted.

BACKGROUND

The following allegations are taken from the complaint and are accepted as true on this motion to dismiss. *See Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1174 (2d Cir.1993).

Defendant GlaxoSmithKline PLC ("GSK") develops, produces and sells pharmaceuticals, over-the-counter medicines, vaccines, and health-related consumer products. Its shares are traded on the London Stock Exchange and as American Depository Shares ("ADSs") on the New York Stock Exchange. GSK markets and sells Avandia, a drug that treats type 2 diabetes, which the United States Food and Drug Administration (FDA) approved in 1999.

In September 2005, GSK finalized its first meta-analysis [FN1] in connection with Avandia. "Glaxo's First Meta-Analysis showed an estimate of excess risk of ischemic cardiovascular events, *i.e.,* an increased risk of heart attack, associated with the use of Avandia."Am. Cmplt. at ¶ 25.

FN1."A meta-analysis is known as the synthesis of research results through the use of an array of statistical methods to cull and merge results from previously performed separate, but related, studies. This type of analysis is done when the individual studies, alone, would not be deemed large enough to adequately examine a particular question."Am. Cmplt. p. 6, n. 3.

On October 27, 2005, GSK issued a press release announcing its financial results for its third quarter of 2005. It reported earnings of 21.3 pence per share, up from 17.7 pence per share for its third quarter of 2004. The press release described Avandia as one of the "key products" contributing toward GSK's "excellent pharmaceutical sales growth." *Id.* at ¶ 42.That day, GSK hosted a conference call with analysts and investors, during which defendant David Stout (GSK's President of Pharmaceutical Operations) stated: "Obviously we've had tremendous success with Avandia, but I want to continue to-to emphasize that we do not expect the growth rate to slow down over the next couple of years."*Id.* at ¶ 44.

On February 8, 2006 GSK issued a press release announcing its financial results for the fourth quarter of 2005 and fiscal year 2005. Dr. Jean-Pierre Gamier (GSK's Chief Executive Officer) stated "Looking into 2006, the strong growth seen from key products such as Seretide/Advair, *Avandia* and from our vaccines business is set to continue...."*Id.* at SI 46 (emphasis added in Am. Cmplt.). The press release stated *"Avandia/Avandamet* (18% to £1.3 billion) continues to maintain its leadership position in the TZD [thiazolidinedione] class of anti-diabetic agents."*Id.* (emphasis added in Am. Cmplt.). During a conference call with analysts and investors that day, Stout stated "We still see Advair, Seretide, and *Avandia* as well as our vaccine portfolio as *significant growth drivers. Id.* at ¶ 47 (emphasis added in Am. Cmplt.).

In January 2006 GSK had begun a second meta-analysis of Avandia, incorporating five additional studies which had been completed between September 2004 and August 2005. The results were

finalized in March 2006 and "showed an estimate of excess risk of ischemic cardiovascular events associated with the use of Avandia that was even greater than the risk portrayed in the First Meta-Analysis."*Id.* at ¶ 26.

***2** On March 3, 2006 GSK filed its 2005 Annual Report with the SEC which stated "Looking into 2006, the strong growth seen from key products [including Avandia] and from our vaccines business is expected to continue...."*Id.* at ¶ 49.It also stated: "Sales growth of existing products and launch of new products are key drivers of GSK's business performance. *The strong growth seen from key products such as* Seretide/Advair, *Avandia* /Avandamet and from GSK's vaccines business is expected to continue in 2006."*Id.* (emphasis added in Am. Cmplt.).

Plaintiffs allege that those statements "were each materially false and misleading."*Id.* at ¶ 50."In addition, at the time the statements were made, Defendants were aware of Glaxo's (more expansive) Second Meta-Analysis, which showed an estimate of excess risk of ischemic cardiovascular events associated with the use of Avandia that was even greater than the risk portrayed in the First Meta-Analysis. Based on this adverse information, coupled with the results from the First Meta-Analysis, Defendants lacked a reasonable basis for their positive statements about Avandia and its growth prospects."*Id.*

On April 27, 2006, GSK issued a press release announcing earnings of 26.5p per share for the first quarter of 2006, up from 21.1p per share for the first quarter of 2005. In the press release, which was filed with the SEC, GSK called Avandia one of its "key growth drivers." *Id.* at ¶ 51.

On July 26, 2006 GSK issued a press release announcing earnings of 23.3p per share for the second quarter of 2006, up from 20.4p per share for the second quarter of 2005. "Defendant Gamier, in 'commenting on the performance in the quarter and GSK's outlook' attributed the Company's ability 'to raise our earnings guidance' for 2006 to pharmaceutical sales growth, including a 32% increase in sales of Avandia."*Id.* at ¶ 53.

In August 2006, GSK provided the FDA with a meta-analysis of 42 separate, randomized, controlled clinic trials to assess the efficacy of Avandia for treatment of type 2 diabetes compared with placebo and other treatments."According to the FDA, it did not publicly discuss the data submitted by Glaxo at the time it was submitted in August 2006 because the FDA wanted to wait until it was able to perform a comprehensive internal re-analysis of that data."*Id.* at ¶ 27."Despite knowing that the data of the Company's meta-analyses showed an increased risk of heart attacks associated with the use of Avandia, Defendants did not disclose this material information to investors during the Class Period. Instead, Defendants repeatedly highlighted the success of Avandia's sales and the sizeable contribution those sales made to the overall performance and growth of Glaxo without disclosing the material adverse facts they were aware of."*Id.* at ¶ 28."Moreover, at the same time Defendants were aware of the conclusions from their own meta-analyses, they repeatedly positively highlighted studies which, according to Defendants, demonstrated that Avandia showed (or will show) no increase in myocardial infarctions or cardiovascular-related deaths."*Id.* at ¶ 29."Throughout the Class Period, analysts recommended Glaxo to investors based on Defendants' representations from ... studies that the risks of cardiovascular events related to Avandia were minimal."*Id.* at ¶ 30.

***3** On October 26, 2006, GSK issued a press release announcing its financial results for the third quarter of 2006, which reported earnings up from 21.3 pence per share for the previous quarter. It stated "The Avandia family of products, for the treatment of type 2 diabetes, continues to perform well with sales up 11% to £378 million in the quarter."*Id.* at ¶ 55.It also stated:

> In September, results of the landmark DREAM study were presented to the European Association for the Study of Diabetes. These data demonstrated that Avandia reduced the risk of developing type 2 diabetes by 62% relative to placebo, among people at high risk of developing type 2 diabetes. This highly statistically significant reduction of 62% ($p<0.0001$) was additive to standard counseling on healthy eating and exercise, and is the first evidence that Avandia can reduce the risk of progression from pre-diabetes to type 2 diabetes in high-risk patients.

Id."In summary, Glaxo reported that its review of the cardiovascular data in the DREAM study showed no increased risk for myocardial infarctions or cardiovascular-related deaths from the use of Avandia."*Id.* at ¶ 29.

During a conference call on October 26, 2006, Dr. Gamier discussed Avandia, stating: "This is a big engine. This is not a product that is going to stall anytime soon, and we are prepared to back it up in a way that's going to be a big driver for the Company for years to come."*Id.* at ¶ 56.

On February 8, 2007 GSK issued a press release announcing its financial results for the fourth quarter of 2006 and the fiscal year 2006, which reported earnings from the fiscal year 2006 of 95.5 pence per share, up from 82.6 pence per share for the year 2005. *Id.* at ¶ 58.It highlighted the financial contribution made by sales of Avandia and its own ADOPT ("A Diabetes Outcome Progression Trial") study which indicated the positive attributes of Avandia, and "reported that its review of the data in the ADOPT study showed no statistically significant differences in cardiovascular-related deaths or myocardial infarctions."*Id.* at ¶¶ 29, 58.GSK's 2006 Annual Report stated: "Sales growth of existing products and launch of new products are key drivers of GSK's business performance. *The strong growth seen from key products such as ...Avandia... is expected to continue in 2007."Id.* at ¶ 62 (emphasis added in Am. Cmplt.).

On May 21, 2007, the *New England Journal of Medicine* published a meta-analysis by Dr. Stephen Nissen which concluded that patients taking Avandia are at an increased risk for heart attacks. *Id.* at ¶ 32.That same day, the FDA issued a safety alert addressing risks identified by its own analysis of completed controlled clinical trials, which demonstrated a potentially significant increase in the risk of heart attacks and heart-related deaths in patients taking Avandia. *Id.* at ¶ 31."As a result of Dr. Nissen's published findings on May 21, 2007 and the FDA's safety alert that same day, the price of Glaxo ADSs dropped $4 .53 per share, or 7.8%, and the price of Glaxo's ordinary shares dropped 74 pence, both on unusually high trading volume."*Id.* at ¶ 33.

***4** On July 9, 2007, *The Wall Street Journal* published an article about GSK and Avandia, which reported an interview of Dr. Garnier:

> WSJ: Has Glaxo done everything it could to study Avandia and communicate its risks to the public?
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> Dr. Gamier: We're not perfect, I'm sure. With 20-20 hindsight we could have done more.

Id. at ¶ 35; Jeanne Whalen, *Boss Talk: Glaxo's Garnier is Taking the Heat-Defending Safety of Avandia Preoccupies, But Doesn't Consume, Drug Company's CEO,* Wall St. J., July 9, 2007, at B1 (Defs.' Ex. 42).

The amended complaint states: "When analysts became aware of Dr. Nissen's findings and the corresponding risk of heart attack associated with Avandia, analysts downgraded Glaxo. The downgrades were attributed to the sales losses and negative earnings impact that Avandia's risk of heart attacks would have on Glaxo's overall company performance."Am. Cmplt. at ¶ 37.

On June 7, 2007, Bear Stearns stated: "In view of the risks to GSK's U.S. Avandia franchise, we have reduced our Avandia forecasts."*Id.* at ¶ 38.In July 2007, an FDA advisory committee agreed that Avandia was tied to an increased risk of heart attacks. *Id.* at ¶ 36.On July 25, 2007, Bear Steams stated: "Since May 23, 2007, when Dr. Nissen's meta-analysis on Avandia's CV risk profile was published in the *NEJM,* GSK shares have come off 5.4% *to reflect the expected earnings impact.*We cut our Avandia sales projections on June 8, 2007 ...." *Id.* at ¶ 39 (emphasis added in Am. Cmplt.).

This suit was filed on June 11, 2007, and on October 5, 2007 the Court appointed Avon Pension Fund, administered by Bath & North East Somerset Council, and North Yorkshire County Council, administering authority for the North Yorkshire Pension Fund, as lead plaintiffs.

On November 13, 2007, plaintiffs filed an amended complaint, which defendants now move to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) for failure to state a claim.

DISCUSSION

Under Fed.R.Civ.P. 12(b)(6), on a motion to dismiss a complaint for failure to state a claim upon which relief may be granted, a court must accept the factual allegations of the complaint as true, and draw all inferences in favor of the plaintiff. *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1174 (2d Cir.1993). The court may consider exhibits annexed to the complaint or incorporated in it by reference. *Brass v. American Film Technologies, Inc.*, 987 F.2d 142, 150 (2d Cir.1993)."In order to withstand a motion to dismiss, a complaint must plead enough facts to state a claim for relief that is plausible on its face."*Bell Atl. Corp. v. Twombly*, 127 S.Ct. 1955, 1974 (2007).

To state a claim under Section 10(b) and Rule 10b-5, plaintiff must plead (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 342 (2005).

***5** Defendants argue that the Court should dismiss the amended complaint because plaintiffs have not established that defendants made a material misrepresentation or omission, plaintiffs do not sufficiently plead scienter, and the statements plaintiffs identify as false and misleading are forward-looking statements and thus are not actionable.

1. Material Misrepresentation or Omission

Defendants urge that plaintiffs' claims should be read as asserting that "several otherwise accurate statements regarding increased sales of Avandia, opinions regarding the future prospects of Avandia, and disclosures reporting the results of certain long term studies of Avandia were rendered materially misleading by the absence of any reference to GSK's meta-analysis regarding Avandia's cardiovascular safety."Defs.' Dec. 13, 2007 Mem. p. 31. They argue that the omission was not material because the meta-analyses results were inconclusive and thus GSK had no duty to disclose them.

Plaintiffs assert that "The positive statements made about Avandia and its contribution to the Company's financial results created an obligation to disclose the then-known adverse facts concerning the risks and safety issues attendant to the use of Avandia."Am. Cmplt. ¶ 43.

"Silence, absent a duty to disclose, is not misleading under Rule 10b-5."*Basic Inc. v. Levinson*, 485 U.S. 224, 239, n. 17 (1988). For an omission to be "material", "there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available."*Id.* at 231-232, quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976).

In *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153 (2d Cir.1998) (*"Carter-Wallace I"*), the plaintiffs alleged that the manufacturer of an anti-epileptic medication was liable for securities fraud because it failed to disclose adverse event reports from users of the medication. The Second Circuit found that there was no duty to disclose the adverse event reports before the date on which the manufacturer and the FDA issued a joint letter recommending that most patients stop taking the medication. The Second Circuit stated:

> Drug companies need not disclose isolated reports of illness suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by- rather than randomly associated with-use of the drugs and are sufficiently serious and frequent to affect future earnings.

Carter-Wallace I, 150 F.3d at 157.

The Amended Complaint nowhere alleges that GSK's meta-analyses results provided statistically significant evidence that Avandia caused cardiovascular risks. The most it claims is that the meta-analyses showed an "estimate" that an increased risk of heart attack was "associated" with the use of Avandia. *See* Am. Cmplt. ¶¶ 25, 26, 28, 50. That is not a claim that defendants knew that risk was either statistically significant, or sufficiently serious or frequent to affect Avandia's future earnings. Accordingly, it does not state a legal claim that those meta-analyses imposed a duty on GSK to disclose them. *See In re Bayer AG Sec. Litig.*, 2004 WL 2190357, at *10 (S.D.N.Y. Sept. 30, 2004) (following *Carter-Wallace I* and finding no duty to disclose adverse events reports until "defendants viewed the adverse event reports as 'sufficiently

serious and frequent to affect future earnings.' ").

*6 In August 2006 GSK disclosed the results of the 42 clinical trials underlying the two meta-analyses, which were comprehensively re-analyzed by the FDA until it issued its safety alert on May 21, 2007 and stated:

> The U.S. Food and Drug Administration (FDA) is aware of a potential safety issue related to Avandia (rosiglitazone), a drug approved to treat type 2 diabetes. Safety data from controlled clinical trials have shown that there is a potentially significant increase in the risk of heart attack and heart-related deaths in patients taking Avandia. However, other published and unpublished data from long-term clinical trials of Avandia, including an interim analysis of data from the RECORD trial (a large, ongoing, randomized open label trial) and unpublished reanalyses of data from DREAM (a previously conducted placebo-controlled, randomized trial) provide contradictory evidence about the risks in patients treated with Avandia.
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> ....
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> FDA's analyses of all available data are ongoing. FDA has not confirmed the clinical significance of the reported increased risk in the context of other studies. Pending questions include whether the other approved treatment from the same class of drugs, pioglitazone, has less, the same or greater risks. Furthermore, there is inherent risk associated with switching patients with diabetes from one treatment to another even in the absence of specific risks associated with particular treatments. For these reasons, FDA is not asking GlaxoSmithKline, the drug's sponsor, to take any specific action at this time.

Am. Cmplt. ¶ 27; Defs.' Ex. 26.

On June 6, 2007, FDA Commissioner von Eschenbach appeared before the United States House of Representatives' Committee on Oversight and Government Reform and stated: [FN2]

> FN2. This statement is incorporated into the amended complaint, because the language is quoted almost verbatim in paragraph 27.

> In August 2006, the manufacturer of Avandia, GlaxoSmithKline (GSK or the company), provided FDA with a pooled analysis (meta-analysis) of 42 separate double blinded, randomized, controlled clinical trials to assess the efficacy of rosiglitazone for treatment of type 2 diabetes. At the same time, the company also provided a population-based database study discussed below. The pooled analysis and the population-based database study presented inconsistent data with regard to the potential cardiovascular risk of rosiglitazone. Since then, results of other long-term controlled clinical studies have been published or unpublished results have been made available to FDA. In looking at all the studies to date related to the potential contribution of rosiglitazone to increasing the risk of heart attack, the data are inconsistent and conclusions are not clear.
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> ....
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> Let me describe FDA's public communication about the data related to risk for heart attacks. FDA did not publicly discuss the data submitted by GSK at the time it was submitted in August 2006, because the data from the pooled analysis and the population based study were inconsistent and we began a comprehensive re-analysis of those data.

*7 Defs.' Ex. 15, pp. 3-5.

Thus the statements referred to in the amended complaint do not show that the heart attack risk was either statistically significant or sufficiently serious or frequent to affect Avandia's future earnings. "Companies conduct many experiments and tests in connection with their products, and to require the public announcement of each one would risk 'bury[ing] the shareholders in an avalanche of trivial information.' " *San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Co.*, 75 F.3d 801, 810 (2d Cir.1996), quoting *TSC Indus.*, 426 U.S. at 448.

GSK had no duty to disclose the results of its meta-analyses, and the amended complaint does not sufficiently plead that defendants made a material omission.

2. Scienter

The Private Securities Litigation Reform Act ("PSLRA") requires that a complaint "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind."15 U.S.C. § 78u-4 (b)(2). The requisite state of mind in a Rule 10b-5 action is "an intent to deceive, manipulate or defraud ."*Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976). The Supreme Court stated in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S.Ct. 2499, 2504-2505 (2007):

> It does not suffice that a reasonable factfinder plausibly could infer from the complaint's allegations the requisite state of mind. Rather, to determine whether a complaint's scienter allegations can survive threshold inspection for sufficiency, a court governed by § 21D(b)(2) must engage in a comparative evaluation; it must consider, not only inferences urged by the plaintiff, as the Seventh Circuit did, but also competing inferences rationally drawn from the facts alleged. An inference of fraudulent intent may be plausible, yet less cogent than other, nonculpable explanations for the defendant's conduct. To qualify as "strong" within the intendment of § 2ID(b)(2), we hold, an inference of scienter must be more than merely plausible or reasonable-it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.

To satisfy the scienter requirement, a complaint must allege facts "(1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness."*ATSI Communs., Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir.2007).

A. *Motive and Opportunity*

Defendants do not dispute that they had the opportunity to defraud shareholders, but they argue that plaintiffs have not sufficiently pled motive.

Plaintiffs argue that defendants had the motive to artificially inflate GSK's stock price to enable the individual defendants to sell their personal holdings for a profit.

In *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir.2001), quoting *Novak v. Kasaks*, 216 F.3d 300, 307-08 (2d Cir.2000), the Second Circuit stated:

> ***8** Sufficient motive allegations " 'entail concrete benefits that could be realized by one or more of the false statements and wrongful nondisclosures alleged.' " Motives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from the fraud.

For insider trading activity during the class period to support an inference of bad faith and scienter, it must be "unusual." *Acito v. IMCERA Group*, 47 F.3d 47, 54 (2d Cir.1995). To determine whether the trading activity is "unusual" courts consider "the amount of profit from the sales, the portion of the stockholdings sold, the change in volume of insider sales, and the number of insiders selling."*In Re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 75 (2d Cir.2001).

The amended complaint alleges that seven insiders traded 503,531 shares of GSK stock in fourteen transactions during the class period for proceeds totaling approximately $27.5 million. Am. Cmplt. ¶ 70. However, only four transactions were made by defendants in this case, for proceeds totaling under $6.5 million. Misconduct by non-defendants cannot be used to allege defendants' scienter "without adequate factual allegations that those defendants engaged in misconduct or knew that their disclosures were false."*In re Marsh & McLennan Cos. Sec. Litig.*, 501 F.Supp.2d 452, 485 (S.D.N .Y.2006). Additionally, the amended complaint does not allege that two of the four individual defendants, Julian Heslop (GSK's Chief Financial Officer) and Simon Bicknell (GSK's Secretary), engaged in any sales transactions during the class period.

The amended complaint does not contain any information on the amount of profits from the sales, the portion of defendants' stockholdings sold, or the change in volume of insider sales. Without context, plaintiffs' conclusory statement that the transactions were "unusual and suspicious" is insufficient to allege fraudulent intent.

B. *Conscious Misbehavior or Recklessness*

To state a claim of scienter based on recklessness, plaintiffs must have specifically alleged that "defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation."*Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir.2000). Defendants do not deny that they had access to the reports associating Avandia with cardiovascular risks. They argue, however, that the results were inconclusive and therefore their failure to disclose those results to the public did not misrepresent material facts related to GSK. As discussed above, defendants did not have an obligation to disclose that information.

Allegations of defendants' intent to defraud by suppressing negative data are inconsistent with defendants' disclosure of that data on GSK's website and to the FDA. GSK disclosed its meta-analyses results to the FDA, and posted them to its website, which rebuts any intent to defraud by concealing information.

***9** Plaintiffs argue that Dr. Gamier's statement in the July 9, 2007 Wall Street Journal Article that "We're not perfect, I'm sure. With 20-20 hindsight we could have done more" acknowledges GSK's intentional failure to adequately communicate Avandia's risks. However, in the context of the article as a whole, that statement does not demonstrate defendants' intent to mislead. The article stated:

> Dr. Gamier is now trying to fight research with research. He says Glaxo performed its own meta-analysis of Avandia before Dr. Nissen's-and also found a risk of heart attack. But the risk was very slight, and was outweighed by other evidence showing that Avandia is as safe for the heart as other diabetes drugs, Dr. Gamier says. The Food and Drug Administration is now carrying out its own meta-analysis and will convene a panel of medical advisers on July 30 to weigh the evidence.
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> WSJ: Has Glaxo done everything it could to study Avandia and communicate its risks to the public?
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> Dr. Garnier: We're not perfect, I'm sure. With 20-20 hindsight we could have done more. But I have to say in the case of Avandia, you see that we were diligent from the day of the launch to start to study the drug in some depth in [clinical] studies and then we did the meta-analysis a year ahead of Dr. Nissen.
>
> As soon as we found out that there was at least a question raised by the meta-analysis, we immediately did the epidemiology study with 30,000 patients that came out absolutely squeaky clean and supportive of Avandia. So you look at the totality, Avandia is by far the most studied diabetic agent on the market today. So sure, maybe we could do more, but frankly the record is very good. Not only have we studied this drug right, left and center, but also we have been transparent, informed everybody.

Defs.' Ex. 42.

Taken as a whole, Dr. Garnier's statement does not support an assertion that defendants acted with the requisite state of mind at the time of the alleged fraud.

In *In re Carter-Wallace Sec. Litig.*, 220 F.3d 36, 42 (2d Cir.2000) (*"Carter-Wallace II"*), the Second Circuit found that until the establishment of a statistical link between Felbatol and any adverse side effects, there was no strong inference of fraudulent intent:

> Here, the early medical reports may have indicated a potential problem, but until a connection between Felbatol and any illness could be made, we would not expect Carter-Wallace to abandon its product on what, at the time, would have been speculation. The complaint here cannot support an inference that Carter-Wallace turned a blind eye to the reports of adverse side effects. There is no indication that Carter-Wallace knew, or should have known, of the connection between Felbatol and aplastic anemia before August 1, 1994. Although this connection was subsequently made, the allegations do not support the inference that Carter-Wallace was reckless in failing to have made it earlier.

The amended complaint does not allege that defendants purposefully concealed known conclusive risks from the public. As discussed above, the

Avandia studies and GSK's meta-analyses did not show a decisive link between Avandia and cardiovascular risks. "Because, as discussed earlier, this case does not present facts indicating a clear duty to disclose, plaintiff's scienter allegations do not provide strong evidence of conscious misbehavior or recklessness."*See Kalnit,* 264 F.3d at 143-44.

***10** The amended complaint does not adequately allege a strong inference of scienter.

3. Safe Harbor

Defendants argue that the statements at issue are forward-looking statements, and thus are not actionable under the PSLRA's Safe Harbor provision (15 U.S.C. § 78u-5(c)).

As stated in *High View Fund, L.P. v. Hall,* 27 F.Supp.2d 420, 427 n. 3 (S.D.N.Y.1998), the PSLRA's Safe Harbor Provision "imposes a marginally higher scienter standard for forward-looking statements, requiring proof that the statements were made with 'actual knowledge' of their falsity. 15 U.S.C.A. § 78u-5(c)(1)(B)(i). However, it need not be determined whether the misrepresentations at issue here qualify as forward-looking statements because plaintiffs have failed adequately to plead the lower scienter standard."

Leave to Replead

Plaintiffs request leave to replead the complaint based on "newly discovered information" about Avandia's connection to increased cardiovascular risks.

Plaintiffs' second amended complaint would include an additional study linking Avandia to an increased risk of heart attack. However, that study was published on December 12, 2007, almost seven months after the end of the class period, and thus its addition would not help plaintiffs adequately allege defendants' state of mind during the class period.

Plaintiffs also seek to add details of a November 2007 Senate Committee Staff Report that claimed GSK intimidated Dr. John Buse, a diabetes expert, to silence his concerns about Avandia's negative cardiovascular effects.

The Staff Report states: "Based on the documents in the Committee's possession, it appears that Dr. Buse remained silent about his concerns regarding Avandia for approximately two years. However, in 2005, he once again privately voiced his opinion that Avandia carried cardiovascular risks."Pl.'s Mem. Ex. A, p. 8. In an e-mail to Dr. Nissen dated October 23, 2005, Dr. Buse wrote about GSK: "I was certainly intimidated by them but frankly did not have the granularity of data that you had and decided that it was not worth it.... Again congratulations on that very important piece of work. It makes me embarrassed to have caved several years ago."*Id.* Therefore, while in 1999-2000 GSK might have suppressed Dr. Buse's concerns about Avandia, by October 2005, during the class period, Dr. Buse was conveying his concerns and was no longer silent. Dr. Buse's views were not excluded from the "total mix" of information available to the class.[FN3]

> FN3. The evidence regarding Dr. Buse is not "newly discovered." On June 6, 2007, before the original complaint was filed in this action, the U.S. House of Representatives' Committee on Oversight and Government Reform held an oversight hearing on the FDA's role in evaluating Avandia's safety, in which Dr. Buse discussed his interactions with GSK. That hearing and those interactions were mentioned in a brief filed in this case associated with a motion to be appointed lead plaintiff, two months before plaintiffs filed their amended complaint. *See* Sept. 7, 2007 Institutional Investor Group Mem. pp. 11-12, n. 14.

Leave to replead is denied, because the proposed additions to the amended complaint would be futile.

CONCLUSION

Defendants' motion to dismiss the amended complaint is granted. Plaintiffs' request to replead is denied.

So ordered.

S.D.N.Y.,2008.

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Slip Copy, 2008 WL 2073421 (S.D.N.Y.)

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